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10/602,171	06/23/2003	Richard L. Mueller JR.	ACU-126	9435

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EXAMINER

TOOR, SADAF A

ART UNIT PAPER NUMBER

3736

DATE MAILED: 11/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/602,171	Applicant(s) MUELLER, RICHARD L.	
	Examiner Sadaf Toor	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7, 9-24, 26 and 27 is/are rejected.
- 7) ☒ Claim(s) 8 and 25 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 June 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |  |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____  |

**DETAILED ACTION*****Drawings***

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: 220 and 222 in Fig. 4. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.
2. The drawings are objected to because reference numeral "416" in Fig. 6B apparently should be changed to --426--. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of

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the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### *Specification*

3. The abstract of the disclosure is objected to because "the collection vessel" in line 5 apparently should be replaced by --a collection vessel--. Correction is required. See MPEP § 608.01(b).
4. The disclosure is objected to because of the following informalities:
  - a. "Begins" on page 1, line 20 apparently should be changed to --begin--.
  - b. The word --brush-- should be inserted after "biopsy" on page 2, line 5.
  - c. The word --a-- should be inserted between "is" and "side" on page 3, line 8.
  - d. "14" apparently should be changed to --13-- on page 4, line 6 to be consistent with the reference numerals in lines 4-5 on page 4.
  - e. "555" apparently should be replaced by --535-- on page 8, line 22.

Appropriate correction is required.

### *Claim Rejections - 35 USC § 112*

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 11-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claim 11 recites the limitation "the elongated housing" in line 2. There is insufficient antecedent basis for this limitation in the claim. Claims 12-14 are also rejected for depending from claim 11.

***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-6 and 15-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Suci et al. ('537). Suci et al. teach an endometrial cytology brush. The cytology brush comprises a bristle shank (shaft 22), a bristle structure on the shank having bristles (14), a brush handle (20), and a couple for releasably attaching the bristle shank to the brush handle (see Fig. 9 and corresponding parts of the description). Regarding claim 2, rounded bead 16 and edge 17 provide an atraumatic tip as taught in column 4, lines 42-48. Referring to claim 3, Suci et al. teach that the bristles may be nylon bristles (see column 4, lines 34-35). Regarding claims 4 and 17, elements 34 and 36 in Fig. 9 appear to illustrate a threaded connection. Regarding claims 5-6 and 18-19, Suci et al. teach that the brush and shaft are "removably engaged" with the handle (see column 5, lines 30-34). Examiner interprets "engaged" to imply a friction connection. Element

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36 of Fig 9., although not addressed in the description, appears to be a female end of a connection or collar.

***Claim Rejections - 35 USC § 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 7 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Suci et al. ('537) in view of Ouchi ('850). As discussed above, Suci et al. teach a cytology brush having a bristle shank with bristles of sufficient stiffness to loosen cytology material without traumatization to the tissue, a handle, and a coupling for releasably attaching the bristle shank to the brush handle. However, Suci et al. fail to teach that the coupling is a claw carried by the bristle shank and releasably engaging the bristle shank. Ouchi teaches a treatment accessory for an endoscope. In column 2, lines 11-14, Ouchi teaches that the treatment accessory may be a cytology brush including a bristle portion. Figures 2B and 4-6 best illustrate the brush having a claw (openable portions 14A) which releasably engages the bristle shank (12). Ouchi teaches that when the brush is retracted into the elongated housing (11), the claw (14A) opens to fit the inner surface of the shank (12) and also serves to protect the brush (2) and retain a number of cells on the bristles (see column 6, lines 26-32). It would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to provide a cytology brush similar that

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taught by Suci et al. with a claw as taught by Ouchi to provide a means for releasably engaging the bristle shank and protecting the cells during retraction of the brush.

12. Claims 9, 11-13, 21-24, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Suci et al. ('537) in view of Vermeulen ('323). As discussed above, Suci et al. teach a cytology brush having a bristle shank with bristles of sufficient stiffness to loosen cytology material without traumatization to the tissue, a handle, and a coupling for releasably attaching the bristle shank to the brush handle. However, Suci et al. fail to teach an elongated housing for the brush handle and a biopsy site marker releasably carried by the cytology brush in the elongated housing. Suci et al. also fail to teach a detent for limiting axial travel of the brush handle within the elongated housing, that the handle is slidably received in the housing, the detent is removably secured to the brush handle, and the housing is tubular. Vermeulen teaches a cytology brush which includes an elongated tubular housing (outer sheath 106). Regarding claims 9 and 21, the Vermeulen brush also includes a biopsy site marker (120) carried by the bristle shank (102) in the elongated housing (106). Referring now to claims 11-13 and 22-24, Vermeulen teaches a detent (retainer clip 132), which is removably secured to the housing, for limiting axial travel of the brush within the elongated housing (106). Ends 134 and 136 of the detent (132) coordinate with grooves 116 and 128 integrating the clip into the housing (see Fig. 1 and 3). Column 4 lines 1-27 detail the operation of the brush and use of the detent (132) to limit longitudinal movement of the brush within the housing and protect the bristles until the brush reaches the cytology location. It would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to provide a cytology brush similar that taught by Suci et al. with an elongated housing, biopsy markers, and detent similar to that taught by the Vermeulen

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cytology brush to provide protection for the bristles during insertion and placement of the brush in the cytology location and a means for recording the location of the cytology site.

13. Claims 10 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Suciu et al. ('537) in view of Vermeulen ('323) as applied to claims 9 and 24 above, and further in view of Sirimanne et al. ('324). As discussed above, the Suciu et al. cytology brush, with the modifications of the Vermeulen cytology brush, teaches all the limitations of the claims except that the biopsy site marker is an outwardly biased coil or a titanium coil. Sirimanne et al. teach a marking device and method. Sirimanne disclose an outwardly biased coil which conforms to the shape of the cavity of interest (see Fig. 5D and corresponding parts of the description). Paragraph [0060], line 10 teaches that the coil can be made of titanium. It would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to provide a cytology brush similar to that of Suciu et al. and Vermeulen with the biopsy site marker being an outwardly biased coil made of titanium as taught by Sirimanne et al. to provide a means for locating the cytology site for follow-up examination (see paragraphs [0004] and [0005]).

***Allowable Subject Matter***

14. Claims 8 and 25 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.



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15. Claim 14 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

16. The following is a statement of reasons for the indication of allowable subject matter: Regarding claim 8, no prior art of record teach or fairly suggest a cytology brush having a bristle shank, a bristle structure on the shank having bristles, a brush handle, and a claw or corkscrew couple for releasably attaching the bristle shank to the brush handle. Regarding claim 25, no prior art of record teach or fairly suggest a cytology brush having a bristle shank, a bristle structure on the shank having bristles, a detachable brush handle, a dispensable opaque marker, and a pivotable arm to serve as a detent on a housing. Regarding claim 14, no prior art of record teach or fairly suggest a cytology brush having a bristle shank, a bristle structure on the shank having bristles, a brush handle, a coupling for releasably attaching the bristle shank to the handle, and a detent mounted to an elongated housing in a hinged relationship.

### ***Conclusion***

17. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Yim ('265) teaches a brush assembly for obtaining endocervical tissue samples. Fig. 8 illustrates the brush comprising two interconnecting shafts. Lonky et al. ('044) teach a brush with bristles for collection of cells in an oral cavity where a brush head may be attached to a handle by a threaded connection. Sussman ('195) teaches a brush including a bristle shank with a bristle structure that is frictionally coupled to a handle by a collar.

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18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sadaf Toor whose telephone number is (571) 272-4734. The examiner can normally be reached on Monday - Friday, 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

sat  
11/18/04

  
CHARLES MARMOR  
PRIMARY EXAMINER